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for special dietary use, it shall be labeled in compliance with part 105 of this chapter.

[63 FR 16433, Apr. 3, 1998, as amended at 64 FR 43909, Aug. 12, 1999]

§ 172.832 Monoglyceride citrate.

A food additive that is a mixture of glyceryl monooleate and its citric acid monoester manufactured by the reaction of glyceryl monooleate with citric acid under controlled conditions may be safely used as a synergist and solubilizer for antioxidants in oils and fats, when used in accordance with the conditions prescribed in this section.

(a) The food additive meets the following specifications:

Acid number, 70–100.

Total citric acid (free and combined), 14 percent–17 percent.

(b) It is used, or intended for use, in antioxidant formulations for addition to oils and fats whereby the additive does not exceed 200 parts per million of the combined weight of the oil or fat and the additive.

(c) To assure safe use of the additive:

(1) The container label shall bear, in addition to the other information required by the Act, the name of the additive.

(2) The label or accompanying labeling shall bear adequate directions for the use of the additive which, if followed, will result in a food that complies with the requirements of this section.

§ 172.833 Sucrose acetate isobutyrate (SAIB).

Sucrose acetate isobutyrate may be safely used in foods in accordance with the following prescribed conditions:

(a) Sucrose acetate isobutyrate (CAS Reg. No. 27216-37-1), or SAIB, is the chemical *alpha*-D-glucopyranoside, O-acetyl-tris-O-(2-methyl-1-oxopropyl)-*beta*-D-fructofuranosyl, acetate tris(2-methyl propanoate).

(b) SAIB, a pale, straw-colored liquid, meets the following specifications: (1) Assay: Not less than 98.8 percent and not more than 101.9 percent, based on the following formula:

Assay = $((SV \cdot 0.10586) \div 56.1) \times 100$
Where SV = Saponification value

(2) Saponification value: 524–540 determined using 1 gram of sample by the “Guide to Specifications for General Notices, General Analytical Techniques, Identification Tests, Test Solutions, and Other Reference Materials,” in the “Compendium of Food Additive Specifications, Addendum 4, Food and Agriculture Organization of the United Nations (FAO), Food and Nutrition Paper 5, Revision 2” (1991), pp. 203 and 204, which is incorporated by reference, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(3) Acid value: Not to exceed 0.20 determined using 50 grams of sample by the “Guide to Specifications for General Notices, General Analytical Techniques, Identification Tests, Test Solutions, and Other Reference Materials,” in the “Compendium of Food Additive Specifications, Addendum 4, FAO Food and Nutrition Paper 5, Revision 2,” p. 189 (1991), which is incorporated by reference; see paragraph (b)(2) of this section for availability of the incorporation by reference.

(4) Lead: Not to exceed 1.0 milligrams/kilogram determined by the “Atomic Absorption Spectrophotometric Graphite Furnace Method, Method I,” in the “Food Chemicals Codex,” 4th ed. (1996), pp. 763 and 764, with an attached modification to the sample digestion section in Appendix III.B (July 1996), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Box 285, Washington, DC 20055 (Internet <http://www.nap.edu>), or may be examined at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch

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Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(5) Triacetin: Not to exceed 0.10 percent determined by gas chromatography as described in the "Guide to Specifications for General Notices, General Analytical Techniques, Identification Tests, Test Solutions, and Other Reference Materials," in the "Compendium of Food Additive Specifications, Addendum 4, FAO Food and Nutrition Paper 5, Revision 2," (1991), pp. 13-26, which is incorporated by reference; see paragraph (b)(2) of this section for availability of the incorporation by reference.

(c) The food additive is used as a stabilizer (as defined in § 170.3(o)(28) of this chapter) of emulsions of flavoring oils in nonalcoholic beverages.

(d) The total SAIB content of a beverage containing the additive does not exceed 300 milligrams/kilogram of the finished beverage.

[64 FR 29958, June 4, 1999; 64 FR 43072, Aug. 9, 1999]

§ 172.834 Ethoxylated mono- and diglycerides.

The food additive ethoxylated mono- and diglycerides (polyoxyethylene (20) mono- and diglycerides of fatty acids) (polyglycerate 60) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by:

(1) Glycerolysis of edible fats primarily composed of stearic, palmitic, and myristic acids; or

(2) Direct esterification of glycerol with a mixture of primarily stearic, palmitic, and myristic acids;

to yield a product with less than 0.3 acid number and less than 0.2 percent water, which is then reacted with ethylene oxide.

(b) The additive meets the following specifications:

Saponification number, 65-75.

Acid number, 0-2.

Hydroxyl number, 65-80.

Oxyethylene content, 60.5-65.0 percent.

(c) The additive is used or intended for use in the following foods when standards of identity established under section 401 of the Act do not preclude such use:

Use	Limitations
1. As an emulsifier in pan-release agents for and as a dough conditioner in yeast-leavened bakery products.	Not to exceed levels required to produce the intended effects, total not to exceed 0.5 percent by weight of the flour used.
2. As an emulsifier in cakes and cake mixes.	Not to exceed 0.5 percent by weight of the dry ingredients.
3. As an emulsifier in whipped vegetable oil toppings and topping mixes.	Not to exceed 0.45 percent by weight of the finished whipped vegetable oil toppings.
4. As an emulsifier in icings and icing mixes.	Not to exceed 0.5 percent by weight of the finished icings.
5. As an emulsifier in frozen desserts.	Not to exceed 0.2 percent by weight of the finished frozen desserts.
6. As an emulsifier in edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee.	Not to exceed 0.4 percent by weight of the finished vegetable fat-water emulsions.

(d) When the name "polyglycerate 60" is used in labeling it shall be followed by either "polyoxyethylene (20) mono- and diglycerides of fatty acids" or "ethoxylated mono- and diglycerides" in parentheses.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 37973, July 26, 1977; 50 FR 49536, Dec. 3, 1985]

§ 172.836 Polysorbate 60.

The food additive polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) which is a mixture of polyoxyethylene ethers of mixed partial stearic and palmitic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield a product with a maximum acid number of 10 and a maximum water content of 0.2 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 45-55.